



UNITED STATES PATENT AND TRADEMARK OFFICE

CU

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/720,933

03/01/2001

Elisabeth Henriette Burger

702-002201

8311

28289

7590

06/22/2006

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,933

Applicant(s)

BURGER ET AL.

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35 and 38-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 38-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Prosecution of the instantly claimed invention is hereby reopened and the finality of the previous office action is withdrawn. The Applicants have canceled claims 1-34, and 36-63. Claims 35 and 34-68 are pending.

Obviousness-Type Double Patent Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35, 64-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,638,531 in view of Helmerhorst et al, "Synthetic Histatin Analogues with Broad-spectrum Antimicrobial Activity," *Biochem J*, Vol. 326, 39-45 (1997), presented in the previous office action. The instantly claimed invention is drawn to pharmaceutical compositions and methods of use comprising the peptide LLLFLLKKRKKRKY (SEQ ID NO: 9) and bone material is a pharmaceutical composition that is capable of containing antimicrobial peptides. Hamanishi et al teaches a "tetracalcium phosphate-dicalcium phosphate dihydrate (UCP-DCPD) apatite cement" (bone material) that hardens into a

hydroxyapatite phase that is similar to bone and incorporates (includes) Vancomycin for the treatment of osteomyelitis. Hamanishi teaches that the UCP-DCPD cement can accommodate many drugs without denaturation (if a peptide drug), see page 139 and first paragraph, and page 142 and second column. Hamanishi further teaches the method of mixing the cement powder in a liquid medium in combination with Vancomycin and allowing the bone cement mixture to set. In vivo data is provided in support of the release of the antibiotic and osteomyelitis treatment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 35 and 64-68 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Claims 35 and 64-68 are rejected under 35 U.S.C. (g) based upon claims 1-3 of Patent No. 6,638,531.

Failure to present claims and/or take necessary steps for interference purposes after notification that interfering subject matter is claimed constitutes a disclaimer of the

Art Unit: 1654

subject matter. This amounts to a concession that, as a matter of law, the patentee is the first inventor in this country. See *In re Oguie*, 517 F.2d 1382, 186 USPQ 227 (CCPA 1975).

Applicant's are on record in the remarks filed June 18, 2006, on page 2 and third paragraph as stating:

In order to assert a double-patenting rejection, a patent or patent application and the application at issue must have common ownership. Applicants point out that the present invention and the '531 patent are not commonly owned, as they are assigned to different Assignees. Therefore, Applicants respectfully submit that an assertion of an obviousness-type double patenting rejection against this application in view of the '531 patent is not warranted and should be withdrawn (see page 2 of the response dated May 18, 2006).

The MPEP states, the subject matter developed by another person and the claimed subject matter were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person or involved in a joint research agreement which meets the requirements of 35 U.S.C. 103(c)(2) and (c)(3). In this situation, a rejection under 35 U.S.C. 102(f) /103 or 102(g)/103, or 102(e) /103 for applications filed on or after November 29, 1999 >or pending on or after December 10, 2004<, is precluded (see MPEP 2137.01). Here, Applicants have admitted, on record, that the claimed invention in US 6,638,531 and the instant application did not have common ownership.

As a result, a question arises, under 102(f), as to the inventorship of the subject matter sought to be patented.

Conclusion

No claims are allowed


Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TSH


ANISH GUPTA
PRIMARY EXAMINER